

Attorney Docket No. 1263
S/N: 09/970,624
Reply to Office Action dated 01/06/2004
Page 4 of 8

REMARKS/ARGUMENTS

Claims 1-9 remain in this application. Claims 3 and 8 have been amended. Claim 10 has been withdrawn.

It is noted that the Examiner has withdrawn several objections and rejections. The Examiner's objections to the specification for containing an embedded hyperlink, blank lines and lack of sequence identifier have been withdrawn following appropriate specification amendments. Objections to claims 2, 4, and 8 have been withdrawn. The rejection of claims 1-9 under 35 U.S.C. 101 has been withdrawn in light of the Declaration by Dr. Bruce. The rejection of claims 1-9 under 35 U.S.C. 112, 2nd paragraph was withdrawn in light of claim amendments. The rejection of claims 1-9 under 35 U.S.C. 112, 1st paragraph, for lack of written description, was withdrawn in light of the claim amendments. Also, the rejection of claims 1-9 under 35 U.S.C. 102 (a), 102 (b) and 103 (a) are withdrawn in light of the claim amendments.

CLAIM OBJECTIONS

The Examiner has objected to claim 8 due to informality and suggests that the article --the--, should be inserted in line 4 before "polynucleotide". The Applicant wishes to thank the Examiner for the suggested verbiage. In an effort to particularly point out and more clearly describe the claimed subject matter the Applicant has amended Claim 8 in accordance with the Examiner's request. It is believed that the claim as now stated is free of the objection raised by the Examiner.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112 – Enablement

The Examiner has rejected claims 1-9 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most

Attorney Docket No. 1263
S/N: 09/970,624
Reply to Office Action dated 01/06/2004
Page 5 of 8

nearly connected, to make and/or use the invention. Examiner states that the Applicant has not addressed the aspect of the rejection concerning the production of the claimed transgenic plants, and the claimed method. The Examiner maintains that neither the specification nor the declaration teaches transgenic plants transformed with the claimed nucleic acids. The Examiner states that Heuer et al. teach that SEQ ID NO: 2 is expressed in pollen, and not in roots. Examiner further states that Lorz et al. (WO 01/12798) teaches transiently transformed tobacco pollen cells containing SEQ ID NO:2. The Examiner concludes that given the teachings of Heuer et al., and Lorz et al., it is not clear what effect transgenic expression of the nucleic acids of instant claim 1 would have in transgenic plants.

Also, the Examiner states that the specification provides no teaching as to how one would use transgenic plants in which transgenic expression of the claimed nucleic acid reduced the level of a nitrate-responsive root transcriptional factor, or that modulated the level of nitrate-responsive root transcriptional factor in any other manner. Examiner states that the arguments posed by the Applicant in the last response failed to address the issue that the specification does not teach how one skilled in the art is to use non-bacterial or non-plant host cells.

Applicant traverses. The application as filed contains adequate information to enable one of skill in the art to make and use the invention. The Applicant reminds the Examiner that in section 2164.02 the MPEP states:

"Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed."

Additionally in section 2164.02 the MPEP quotes,

"The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

Applicant reminds the Examiner that actual reduction to practice is not a requirement of patentability, and has not been so since at least 1978.

Attorney Docket No. 1263
S/N: 09/970,624
Reply to Office Action dated 01/06/2004
Page 6 of 8

"...[A]s has long been the law, constructive reduction to practice occurs when a patent application on the claimed invention is filed." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 at 87 (CAFC 1986), citing *Weil v. Fritz*, 572 F.2d 856, 196 USPQ 600 (CCPA 1978).

As stated in the MPEP 2164.05(a) (quoting *in re Buchner*):

"The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public." *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991)

Applicant maintains that there is no obligation to specify production of transformed plants, or the method as claimed. One of skill in the art would have no problem producing plants containing the sequences as claimed. The specification contains complete and detailed descriptions for the polynucleotides claimed, and examples illustrating how to use the same polynucleotides to produce transformed dicot and monocot plants.

Applicant respectfully traverses Examiners statement that Heuer et al. teach that SEQ ID NO: 2 is expressed in pollen, and not in roots. Heuer et al. specifically describe that "ZmMADS2 expression is restricted to pollen and roots" in the Abstract, and ZmMADS expression signal was "observed in root tips and subsequently confirmed by RT-PCR" on page 24. Figure 3, also on page 24, demonstrates the spatial and temporal expression of ZmMADS2, including expression in roots without tips, and root tips. The Heuer reference specifically states that the expression of ZmMADS2 is in both root and the pollen tissues.

Applicant also respectfully traverses Examiner's statement that Lorz et al. (WO 01/12798) teaches transiently transformed tobacco pollen cells, and that since the amino acid sequences of SEQ ID NO:2 and Lorz et al. are identical, the Examiner concludes that it is not clear what effect transgenic expression of the nucleic acids of instant claim 1 would have in transgenic plants. The Lorz reference specifically discloses the direction of "expression in preferably mature, ungerminated pollen tissue but additionally also in root tips" pg 11-12, and "The present invention

Attorney Docket No. 1263

S/N: 09/970,624

Reply to Office Action dated 01/06/2004

Page 7 of 8

relates in particular to pollen and/or root specific expression" pg 20. The Lorz reference includes Figure 1, which shows the spatial and temporal expression of ZmMADS2, Figure 2 which shows ZmMADS2 expression in mature pollen and root tips confirmed by RT-PCR, in Figure 2 the lower band represents amplified ZmMADS cDNA, and the upper band represents genomic DNA.

Therefore, the Applicant reminds the Examiner that the expression of ZmMADS demonstrated in root tissue by these two references when coupled with the Applicant's disclosure, would have allowed one of skill in the art at the time of filing to use the nitrate responsive polynucleotides disclosed to modify expression within transformed plants.

Applicant also wishes to draw the Examiner's attention to a publication attached to this correspondence, Doerner et al., "Control of root growth and development by cyclin expression", Nature, 380 (6574), 520-3, 1996. This article predates our priority date of 10/05/00 by several years, and was therefore readily available to one skilled in the art to which this application pertains. The article addresses changes in lateral-root production in plants exposed to indoleacetic acid by transformation with cyclins. It states that ectopic cyclin expression enhances root growth by stimulation of cell division in meristems, increasing the rate of cell production. The data suggests that cyclin expression is sufficient to enhance growth from established root apical meristems, which indicates that the cell cycle regulates meristem activity. Doerner et al. also illustrates increased lateral root growth in Figure 3. The authors state that cyclin abundance functions as a "rheostat" to allow flexible growth in response to changes in the environment such as nutrient availability. Therefore, with the guidance from Applicant's specification, one of skill in the art at the time of filing would be able to ascertain that the nitrate responsive polynucleotide disclosed in this application could readily be used to modify root growth.

Applicants have provided examples of how to produce transformed monocot and dicot plants and also provided adequate guidance for one of skill in the art to use the polynucleotides in the methods claimed. Applicant maintains that given the

Attorney Docket No. 1263
S/N: 09/970,624
Reply to Office Action dated 01/05/2004
Page 8 of 8

disclosure in the specification, and the knowledge of one of skilled in the art, one would know how to use the transgenic plants in which transgenic expression of the claimed polynucleotides would modify the level of nitrate-responsive transcriptional factor. Also, In an effort to particularly point out and more clearly describe the claimed subject matter, the applicant has amended claim 3, to specify plant host cells.

Conclusion

In view of the above amendments and remarks, Applicant submits that the objection to claim 8 and the rejections of claims 1-9 under 35 U.S.C. §§112, first paragraph for enablement are overcome. Applicant respectfully submits that this application is now in condition for allowance and requests that a timely Notice of Allowance be issued in this case.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

Respectfully submitted,

PIONEER HI-BRED INTERNATIONAL, INC.



Janice L. Deaver
Attorney/Agent for Applicant(s)
Registration No. 52,183

PIONEER HI-BRED INTERNATIONAL, INC.
Corporate Intellectual Property
7100 N.W. 62nd Avenue
P.O. Box 1000
Johnston, Iowa 50131-1000
Phone: (515) 270-3599
Facsimile: (515) 334-6883